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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/630,308

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EXAMINER

BLATT, ERIC D

ART UNIT

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3734

MAIL DATE

DELIVERY MODE

06/07/2010

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/630,308	Applicant(s) RAUKER ET AL.	
	Examiner Eric Blatt	Art Unit 3734	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 16 March 2010.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1,3,4,6-10,12-15,21,22 and 26-29 is/are pending in the application.
- 4a) Of the above claim(s) 15 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1,3,4,6-10,12-14,21,22 and 26-29 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claim 23 is rejected under 35 U.S.C. 103(a) as being unpatentable over Belef et al. (US 7,169,165) in view of Wholey et al. (US 2003/0176886).

Belef discloses a filter delivery catheter (Figures 1B and 3A) comprising an elongated shaft 10 including an aspiration port 16 located along the circumference of the elongated shaft. Although Belef does not directly address aspiration in the embodiments shown in Figures 1B and 3A, Belef does discuss connecting the proximal end of the shaft to a suction source to aspirate embolic material at the distal end of the shaft in other embodiments. (See at least Col. 8, Ln 39-40) Thus, the port 16 is fully capable of being used as an aspiration port. The delivery catheter further includes a blood permeable filtration device 50 having an expanded configuration and a collapsed configuration being sized to fit within the shaft lumen. There is a guidewire 20 slidably disposed within the shaft lumen 11 wherein the guidewire 20 passes through the aspiration port 16.

Belef thus discloses all elements of claim 23 except for additional aspiration ports being disposed distally of the aspiration port 16 and proximally of the distal end of the

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elongated shaft 10. Wholey discloses a similar filter delivery catheter (Figure 7) and teaches that a plurality of aspiration ports 114 may be provided proximate the end of the catheter in order to aspirate embolic debris. It would have been obvious to one of ordinary skill in the art at the time of the invention to modify the apparatus of Belef by providing additional aspiration ports distally of the first port 16 in order to achieve these benefits as taught by Wholey. Examiner notes that claim 23 does not define the proximal and distal directions along the length of the shaft, and that the end of the shaft from which the filtration device is intended to extend may be considered to comprise the proximal end. Upon this interpretation, if the circumferential ports are disposed very close to the tip of the shaft as depicted in Figure 8 of Wholey, these ports will lie proximally of the filtration device when the filtration device is entirely contained within the shaft lumen.

Claims 1, 3, 4, 6-10, 12-14, 21, 22 and 26 are rejected under 35 U.S.C. 103(a) as being unpatentable over Belef et al. (US 7,169,165) in view of Wholey et al. (US 2003/0176886), and further in view of Tao (US 6,610,005).

Belef discloses a filter delivery catheter (Figures 1B and 3A) comprising an elongated shaft 10 including an aspiration port 16 located along the circumference of the elongated shaft. Although Belef does not directly address aspiration in the embodiments shown in Figures 1B and 3A, Belef does discuss connecting the proximal end of the shaft to a suction source to aspirate embolic material at the distal end of the shaft in other embodiments. (See at least Col. 8, Ln 39-40) Thus, the port 16 is fully

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capable of being used as an aspiration port. The delivery catheter further includes a blood permeable filtration device 50 having an expanded configuration and a collapsed configuration being sized to fit within the shaft lumen. There is a guidewire 20 slidably disposed within the shaft lumen 11 wherein the guidewire 20 passes through the aspiration port 16.

Belef thus discloses all elements of claim 1 except for additional aspiration ports being disposed distally of the aspiration port 16 and proximally of the distal end of the elongated shaft 10. Wholey discloses a similar filter delivery catheter (Figure 7) and teaches that a plurality of aspiration ports 114 may be provided proximate the end of the catheter in order to aspirate embolic debris. It would have been obvious to one of ordinary skill in the art at the time of the invention to modify the apparatus of Belef by providing additional aspiration ports proximate the end of the shaft in order to achieve these benefits as taught by Wholey. With regard to the recitations that one or all of the plurality of the aspiration ports is located proximally of the filtration device when the filtration device is contained within the shaft lumen, a configuration wherein only the proximal end of the filtration device is disposed within the shaft lumen may be fairly considered to meet the requirement that the filtration device is contained within the shaft lumen. In such a configuration, all of the ports will be proximal to the filtration device. Concerning the language of claim 21 requiring at least one port to be located proximally of the filtration device when the filtration device is *entirely* contained within the shaft lumen, it appears in Figure 1B that port 16 easily meets this limitation. Since the figures are not necessarily drawn to scale, however, Examiner holds that it would have been

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obvious to one of ordinary skill in the art to change the size of the filter or the position of the port 16 along the shaft length size doing so would merely require optimizing the size and shape of the existing parts of the device.

The filtration device 50 is a floating filter 50 and is fixedly attached to a wire. (Figures 1B and 3A) The aspiration ports are located both along the circumference and along the length of the shaft. A guidewire passes through the proximal most aspiration port 16. Thus, Belef and Wholey teach all elements of claims 1, 3, 4, 6-14, 21, 22 and 26 except for an operable end cap disposed on the elongated shaft distal to the filtration device. Tao discloses a number of end cap embodiments that are fixedly attached to the distal end of a catheter 24 for preventing debris from entering the catheter while it is advanced through a body lumen. (Figures 4-10 and 20-22) It would have been obvious to one of ordinary skill in the art at the time of the invention to further modify the apparatus of Belef by providing an end cap fixedly attached to the end of the shaft 10 in order to achieve these benefits.

Claims 27-29 are rejected under 35 U.S.C. 103(a) as being unpatentable over Belef et al. (US 7,169,165) in view of Wholey et al. (US 2003/0176886) and Tao (US 6,610,005) as applied to claim 1 above, and further in view of Hoy (US 6,705,575).

Regarding claims 27-29, Tao teaches providing an end cap such as that shown in Figure 22 on the distal end of the Belef catheter 10 as discussed above. This end cap comprises a plurality of plates, but it is unclear whether the plates will interleave to any degree during operation. Hoy discloses a device having a related cap-like means

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40 comprising a plurality of overlapping plates 44 (Figures 1 and 5A-5C). It would have been obvious to one of ordinary skill in the art at the time of the invention to provide the plates of the Tao cap such that they interleave since interleaving plates were well known and it causing the plates to interleave would not have produced unexpected results. The plates form a dome shape as shown in Figure 20 of Tao. The shape depicted in Figure 20 may also be considered to generally comprise a cone shape. Alternatively, it would have been obvious to form the plates such that they form a cone shape since this issue is an obvious matter of design choice and would not materially affect the function of the device.

Response to Arguments

Applicant's arguments filed 3-16-2010 have been fully considered but they are not persuasive.

Applicant argues that Belef and Wholey fail to teach the claim limitations regarding the positioning of the aspiration ports with regard to the filtration device. In response, Examiner first notes that the language of claims 1, 3, 4, 6-10, 12-14, 22, and 26-29 require that one (independent claim 1) or all (claim 22) of the ports are disposed proximally of the filtration device when the filtration device is contained within the shaft lumen. A configuration wherein only the proximal end of the filtration device is disposed within the shaft lumen may be fairly considered to meet the requirement that the filtration device is contained within the shaft lumen. Upon this interpretation, all of the ports will be located proximally of the filtration device. The language of claim 21

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requires that one port is disposed proximally of the filtration device when the filtration device is entirely contained within the shaft lumen. As discussed in the body of the rejection, it appears in Figure 1B that port 16 easily meets this limitation. Since the figures are not necessarily drawn to scale, however, Examiner holds that it would have been obvious to one of ordinary skill in the art to change the size of the filter or the position of the port 16 along the shaft length size doing so would merely require optimizing the size and shape of the existing parts of the device. Lastly, claim 23 requires that all of the ports are disposed proximally of the filtration device when the filtration device is entirely contained within the shaft lumen. Claim 23 fails to define the proximal and distal directions along the catheter shaft. Interpreting the end of the shaft out of which the filtration device is deployed to be the proximal end of the shaft, the filtration device may be positioned entirely within the shaft lumen such that all of the ports are located proximally of the filtration device.

Applicant additionally argues that providing an end cap as taught by Tao would prevent the filter from being deployed since the guide wire to which the filter is attached is not disclosed in Belef as being capable of pushing open the proposed end cap. When adding an operable end cap such as those taught in Tao to the system of Belef in order to prevent debris from entering the catheter as it is advanced to the target sight, one skilled in the art could easily optimize the stiffness of hinge 56 (Tao, Figure 4) or petals (Tao, Figure 22) so that the end cap would remain closed during delivery but could be released to allow deployment of the filter. Examiner fails to see how provision of such an end cap would prevent deployment of the filter. With regard to Applicant's

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assertion that one skilled in the art would not be motivated to provide the system of Belef with an end cap taught by Tao since mucous would not be expected to be present within the vasculature, Examiner notes that other forms of debris such as plaque would be present in the vasculature and that this teaching of an end cap is therefore relevant to the Belef device.

Conclusion

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Eric Blatt whose telephone number is (571)272-9735. The examiner can normally be reached on Monday-Friday, 9:00 AM-6:00 PM.

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If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Todd Manahan can be reached on 571-272-4713. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/E. B./

Examiner, Art Unit 3734

***/TODD E. MANAHAN/
Supervisory Patent Examiner, Art Unit 3734***